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T +49 89 / 2399 - 0  
Tx 523 656 epmu d  
Fax +49 89 / 2399 - 4465

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Boards of Appeal

Chambres de recours

Roques, Sarah Elizabeth  
J.A. Kemp & Co.  
14 South Square  
Gray's Inn  
London WC1R 5JJ  
GRANDE BRETAGNE



Datum/Date

27. 07. 07

Zeichen/Ref. Réf.

N.81325A SER

Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°  
00932570.5 - 2406 / 1179012

Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire  
ConjuChem Biotechnologies Inc.

Appeal Number - Board

T0433/05-3304

Please find enclosed a copy of the decision dated 14. 06. 07

The registry:

S. Sanchez Chiquero

Phone: (089) 2399 - 3344

Exhibit B



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Boards of Appeal

Chambres de recours

Naylor, Kathryn May  
Mathys & Squire  
120 Holborn  
London EC1N 2SQ  
GRANDE BRETAGNE



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27. 07. 07

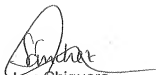
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The registry:

  
S. Sanchez Chiquero

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Case Number: T 0433/05 - 3.3.04

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.04**  
**of 14 June 2007**

**Appellant:**  
(Patent Proprietor)      ConjuChem Biotechnologies Inc.  
Suite 3950, Third Floor  
225 President Kennedy Avenue  
Montreal, QC H2X 3Y8      (CA)

**Representative:**  
Roques, Sarah Elizabeth  
J.A. Kemp & Co.  
14 South Square  
Gray's Inn  
London WC1R 5JJ      (GB)

**Respondent:**  
(Opponent)      TRIMERIS, INC.  
3500 Paramount Parkway  
Morrisville NC 27560      (US)

**Representative:**  
Naylor, Kathryn May  
Mathys & Squire  
120 Holborn  
London EC1N 2SQ      (GB)

**Decision under appeal:**      Decision of the Opposition Division of the  
European Patent Office posted 1 February 2005  
revoking European Patent No. 1179012 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:**      U. Kinkeldey  
**Members:**      M. Wieser  
                 R. Moufang

## **Summary of Facts and Submissions**

- I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 1 179 012, claiming priority from US 60/134,406 (17 May 1999) and US 60/153,406 (10 September 1999), was revoked pursuant to Article 102(1) EPC.
- II. The Opposition Division had decided that the claims of the main request and of auxiliary requests I and III before them did not involve an inventive step contrary to the requirements of Article 56 EPC. The claims of auxiliary requests II and IV were found not to be allowable under Rule 57a EPC.
- III. The Board expressed its preliminary opinion in a communication dated 15 January 2007.
- Oral proceedings were held on 14 June 2007 in the absence of the Respondent (Opponent), who had informed the Board with letter dated 14 May 2007 that he will not be represented at the oral proceedings.
- IV. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the new main request submitted during the oral proceedings.

The Respondent had requested in writing that the appeal be dismissed.

V. Claim 1 of the new main request read as follows:

"Use of a modified anti-viral and antifusogenic peptide in the manufacture of a medicament for preventing and/or treating viral infection, said modified peptide comprising:

a peptide that exhibits anti-viral and antifusogenic activity, and

a maleimide group which is reactive with a thiol group on serum albumin to form a stable covalent bond, wherein the maleimide group is coupled to the peptide either without using a linking group or via a linking group which is (2-amino)-ethoxyacetic acid (AEA) or [2-(2-amino)ethoxy] ethoxy acetic acid (AEEA), said modified peptide forming in vivo an antifusogenic peptide-maleimide-albumin conjugate."

Dependent claims 2 to 16 and 25 refer to preferred embodiments of the use according to claim 1. Claim 17 and dependent claims 18 and 25 refer to the use of a composition comprising certain specific peptides encompassed by claim 1 for the manufacture of a medicament for the prevention and/or treatment of acquired immune deficiency syndrome (AIDS). Claim 19 and dependent claims 20 and 25 refer to the use of a composition comprising certain specific peptides encompassed by claim 1 for the manufacture of a medicament for the prevention and/or treatment of human respiratory syncytial virus (RSV) infection. Claim 21 and dependent claims 22 and 25 refer to the use of a composition comprising certain specific peptides encompassed by claim 1 for the manufacture of a medicament for the prevention and/or treatment of human parainfluenza virus (HPiV) infection. Claim 23 and

dependent claims 24 and 25 refer to the use of a composition comprising certain specific peptides encompassed by claim 1 for the manufacture of a medicament for the prevention and/or treatment of measles virus (MeV) infection.

VI. The following documents are referred to in this decision:

- (1) WO 96/19495
- (4) WO 99/24074
- (8) Proc. Natl. Acad. Sci. USA, Vol.89, 1992, pages 10537 to 10541
- (11) AIDS, Vol.4, 1990, pages 553 to 558
- (12) Annexes I and II to Appellant's letter dated 15 September 2004
- (16) J. Virol., Vol.70, 1996, pages 2982 to 2991
- (17) J. Virol., Vol.69, 1995, pages 3771 to 3777
- (18) Annexes I, II and III to Appellant's letter dated 17 May 2004

VII. The submissions by the Appellant, as far as they are relevant to the present decision, may be summarised as follows:

The patent provided a disclosure of the invention which was sufficient to enable the skilled person to work it

across the entire scope claimed. The Respondent did not provide any evidence that the invention did not work.

The closest state of the art was represented by the disclosure in document (1) which referred to anti-viral and antifusogenic peptides. Due to rapid serum clearance and peptidase and protease activity the in vivo stability of these peptides was unsatisfactory. The problem underlying the patent in suit was the provision of medicaments for the prevention and/or treatment of viral infections having increased in vivo stability whilst at the same time retaining their antifusogenic activity.

This problem was solved by coupling a maleimide group to the peptides, either without a linker or via AEA or AEEA, which maleimide group formed a covalent bond with a thiol group on serum albumin, resulting in an in vivo active antifusogenic peptide-maleimide-albumin conjugate.

The skilled person trying to solve this problem at the relevant date of the invention was aware of various different approaches to extend the in vivo half-life of therapeutically active peptides. Document (4) described the conjugation of opioids to serum albumin via a maleimide group and optionally a linking group like AEA, in order to increase their serum half-life and to prevent them from crossing the blood-brain barrier.

Being aware of the mechanism by which antifusogenic peptides acted, the skilled person would not have considered combining the teaching of document (4) with document (1). If an antifusogenic peptide was modified

such that it was conjugated to a large moiety, such as albumin, the skilled person would have expected the albumin to sterically hinder the antifusogenic peptide and prevent it from accessing its target sequence, i.e. to render the peptide inactive. This was confirmed by the findings in document (16).

The construct disclosed in document (17) was distinguished from the subject-matter of the present claims by the presence of a very long linker of about 117 amino acids, coupling an antifusogenic peptide to a large moiety (maltose binding protein).

Manufacturing a peptide-maleimide-albumin conjugate, having an improved in vivo half life and retaining its antifusogenic activity, could not be derived in an obvious way from the disclosure in the prior art documents on file.

VIII. The submissions by the Respondent, as far as they are relevant to the present decision, may be summarised as follows:

The claims were not entitled to the first priority claimed (US60/134,406; 17 May 1999).

Appellant's new main request should not be admitted into the proceedings as it was late filed.

The prior art did not contain any information, like a reference to the expectation of steric hindrance, that would have deterred a skilled person, trying to solve the problem underlying the patent in suit, to modify the antifusogenic peptides of document (1) by the



method disclosed in document (4) and to form a conjugate with serum albumin in the bloodstream. Documents (11), (17) and (18) provided evidence that molecules up to twice the size of the presently claimed constructs could access the space between the viral membrane and the cell membrane in the viral fusion process without the occurrence of steric hindrance.

The results disclosed in document (16) were obtained by testing the biological activity in a cell fusion assay of oligomers whose molecular mass was much higher than the molecular mass of the presently claimed constructs.

Accordingly, the subject-matter of the claims of Appellant's new main request was obvious in the light of the disclosure in document (1) in combination with document (4).

## **Reasons for the decision**

### *Admissibility*

1. The Respondent requested that the new main request, filed by the Appellant as fifth auxiliary request with the letter setting out the grounds for appeal, dated 8 June 2005, be not admitted into the proceedings as it is late filed.

The claims are distinguished from the claims as granted in so far as claims referring to modified anti-viral peptides have been reformulated as use-claims, referring to the use of the peptides in the manufacture of a medicament. Moreover, the scope of the claims has

been restricted by introducing the feature that the maleimide group is coupled to the peptides either without a linker or via a short linker selected from a group of two specific substances.

These amendments are considered as being a reaction on the outcome of the opposition procedure, where it has been decided that the claims as granted did not involve an inventive step. The amendments have been carried out in a straight forward manner without, *prima facie*, giving rise to formal objections, and have been submitted with the grounds for appeal within the time limit set out in Article 108 EPC. Therefore, the Board does not see any reason not to admit the former fifth auxiliary request which was filed as new main request into the appeal procedure.

*Amendments - Article 123(2) EPC*

2. Claim 1 is based on page 2, lines 26 to 27, page 3, lines 27 to 29, page 11, lines 9 to 11, page 12, lines 8 to 10 and page 13, lines 20 to 26 of the application published as WO 00/69902.

Claims 2 to 24 find a basis in claims 4 to 19, 21, 22, 24, 25, 27, 28 and 30 of the application as published. Claim 25 is especially based on page 12, lines 8 to 10 of the application as published.

The patent has not been amended in a way that it contains subject-matter which extends beyond the content of the application as published.

Claims 1, 17, 19, 21 and 23 differ from the corresponding claims as granted by the insertion of additional technical features, with the effect that the extent of protection conferred had been reduced.

An amendment of granted claims which were directed to a compound and to a composition comprising such compound, so that the amended claims are directed to the use of that compound for a particular purpose, does not result in an extension of the protection conferred, cf decision of the Enlarged Board of Appeal G 2/88, OJ EPO 1990, 93; points (3) to (5).

Accordingly, the Board decides that the requirements of Articles 123(2) and 123(3) EPC are met.

*Priority - Articles 87 to 89 EPC*

3. The first priority document (US 60/134,406; 17 May 1999) does not refer to the anti-viral and antifusogenic peptides whose use is the subject-matter of the claims of Appellant's new main request. This was not contested by the Appellant.

Consequently, this first priority date cannot be validly claimed. The relevant date for the present patent within the meaning of Article 89 EPC is 10 September 1999, the filing date of the second priority document US 60/153,406.

Document (4), international publication date 20 May 1999, belongs therefore to the state of the art according to Article 54(2) EPC.

*Novelty - Article 54 EPC*

4. The Respondent has not argued that the subject-matter of the claims of Appellant's new main request lack novelty.

The subject-matter of claims 1 to 25 is not disclosed in the prior art documents on file and is therefore novel within the meaning of Article 54 EPC.

*Inventive step - Article 56 EPC*

5. As acknowledged by both parties, the closest state of the art is represented by document (1) which discloses anti-viral and antifusogenic peptides including all peptides consisting of SEQ ID NOs 1 to 86 specifically mentioned in the present set of claims (see figures 27 to 30, 47 and 48). The document refers to the use of these peptides for the prevention and/or treatment of viral infections (pages 338 to 341) and mentions on page 11 that the peptides may include modifications and additional amino- and carboxy-groups.
6. The problem underlying the patent in suit according to the new main request is the provision of medicaments for the prevention and/or treatment of viral infections having increased in vivo stability whilst at the same time retaining their antifusogenic activity.
7. The subject-matter of the claims of the patent in suit is distinguished from the disclosure in document (1) in that the anti-viral and antifusogenic peptides are coupled, either without a linker or via AEA or AEEA, to

a maleimide group which is reactive to a thiol group on serum albumin to form a stable covalent bond.

8. After the filing date the Appellant has submitted document (18), consisting of Annexes I, II and III, which contains experimental data showing that DP178 peptides, modified as described in present claim 1, had extended in vivo half-life and displayed anti-viral and antifusogenic activity.
9. When deciding whether the technical problem defined above has indeed been solved by the subject-matter of claim 1 at the relevant date, the Board is aware of Board's 3.3.08 decision T 1329/04, of 28 June 2005. There it is stated that the definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve (point (12) of the reasons for the decision). The Board decided that the post-published evidence submitted in case T 1329/04 could not be regarded as supportive of evidence which would have been given in the application as filed since there was not any. Since the post-published evidence was considered to be the first disclosure going beyond speculation it was not taken into consideration.
10. The same Board confronted with a different technical situation, namely one where the quality of evidence

provided in the respective patent was such that the claimed invention was considered to be a bona fide solution to the problem to be solved, accepted the solution of the problem by taking into consideration also the disclosure in a post-published document (cf decision T 1336/04 of 9 March 2006, point (9) of the reasons for the decision).

11. All specific peptides, defined by their respective SEQ ID NO, used in the manufacture of medicaments according to the claims, in an unmodified form, are known from document (1), where their anti-viral and antifusogenic activity is disclosed.

When evaluating the quality of evidence provided in the patent in suit (and in the application as published), the Board notices that it contains thirty examples concerned with the preparation of modified peptides according to the invention. The use of the modified anti-viral and antifusogenic peptides is described on page 17, the different ways of administration of the modified peptides to patients in need thereof on pages 17 and 18 of the patent. Bonding of the peptides to long-living blood components, like serum albumin, is said to extend the activity of the peptides (page 18, lines 7 to 11), and a method for detecting the extended presence of the modified peptides in a patient's blood by a specific immunoassay is described on pages 18 and 19.

12. Considering decisions T 1329/04 and T 1336/04 (supra), the Board is convinced that the present circumstances are appropriate to take into account supplementary post-published document (18) when establishing whether

the application solves indeed the problem it purports to solve.

In the light of the disclosure in the patent in suit, which is supported by post-published document (18), the Board is satisfied that the problem as determined in point (5) above is solved by the subject-matter of the claims.

13. It remains to be examined if this solution to the problem involves an inventive step, namely if a skilled person would have modified the peptides disclosed in the closest prior art document (1) by coupling them to a maleimide group which reacts with a thiol group on serum albumin.
14. Document (4) discloses antinociceptive agents, preferably opioids coupled with a material providing a functionally reactive group, preferably a maleimide group, which is capable of reacting with a blood component, preferably with serum albumin via a thiol group. The so formed conjugates have extended lifetime in the blood stream (page 2, lines 12 to 16, and page 11, lines 14 to 18) and, due to their size, do not cross the blood-brain or blood-nerve barrier, which prevents them from interfering with other physiological processes (page 8, lines 22 to 27).
15. The Appellant argues that a skilled person bearing in mind the mechanism by which antifusogenic peptides act, would not consider combining the teaching of document (4) with the disclosure in the closest prior art, document (1). The target sequences for antifusogenic peptides are exclusively exposed in a very limited

three dimensional space during the fusion process by which a virus infects a cell. If an antifusogenic peptide is modified such that it is conjugated to a large moiety, such as albumin, the skilled person would expect the albumin to sterically hinder the antifusogenic peptide and prevent it from accessing its target sequence.

Confirmation of this expectation of steric hindrance can, according to the Appellant, be found in document (16), disclosing that an antifusogenic peptide (DP107) as fusion partner with monomeric maltose binding protein (MBP), which has a molecular mass of 44kD, thus about two thirds of the molecular weight of serum albumin, lacks biological activity in a cell fusion assay.

16. Moreover, the Appellant argued that the skilled person at the relevant date of the patent in suit was aware of a plethora of methods to increase the in-vivo half-life of therapeutically active peptides, which all were more promising than the method disclosed in document (4) for the modification of opioids. He names in this respect the production of PEG-derivatives, an extension of the length of the peptide, mutation of the peptides to make them resistant to peptidases, addition of conformation inducers and the inclusion of the peptides in microparticles, microspheres and gels.
17. The Respondent denies that a skilled person at the relevant date of the patent in suit had the expectation that a peptide bound to serum albumin would not fit into the space between the virus membrane and the host cell membrane at the point of virus fusion. On the



contrary, it was known that molecules of twice the size of the conjugates used according to the patent in suit were able to target and bind to the antipusogenic machinery in the gap between the cell and the virus membrane without the occurrence of steric hindrance.

Confirmation for this is said to be found in documents (11), (12) and (17).

Moreover, Appellant's interpretation of the disclosure in document (16) is contested. According to the Respondent, the conjugates found there to be inactive in a cell fusion assay were oligomeric forms, which are about four times bigger than the conjugates of the patent in suit. The fact that steric hindrance was a problem for the authors of document (16) does not mean that it could also be expected to be a problem when using the conjugates according to the present claims.

18. Envelope oligomerization has been thought to serve several crucial functions during the life-cycle of human immunodeficiency virus type 1 (HIV-1). Document (16) is concerned with the determination of the exact oligomeric state of the gp41 leucine zipper region. The zipper motif (DP107) has been expressed as a fusion partner with the monomeric maltose-binding protein (MBP) of *Escherichia coli* and the biophysical properties of this protein were characterized by velocity and equilibrium sedimentation, size exclusion chromatography light scattering and chemical cross-linking analyse (see abstract).

As calculated by SDS-PAGE, the monomeric form of MBP107 migrates with a molecular mass of approximately 50 kDa.

As a control MBP carrier alone was found to migrate with a molecular mass of 44 kDa (see page 2984, right column)

Size exclusion chromatography allowed confirming the multimeric state of the recombinant protein. In these studies MBP107 eluted with a peak with an average molecular mass of 187 kDa, which approximates the molecular mass of a tetramer. In contrast the carrier MBP eluted as a single peak with an average molecular mass of 41 kDa, consistent with the monomeric state of this protein (page 2986, right column).

Velocity sedimentation of MBP107 in the presence of maltose did not alter its sedimentation rate, indicating that protein multimerization occurs through the DP107 - part of the conjugate rather than through the MBP carrier (page 2986, left column, first paragraph).

The authors of document (16) reach the conclusion that the major oligomeric species of MBP107 is tetrameric (page 2988, left column, first full paragraph).

19. Antiretroviral activity of the conjugates is tested in a cell fusion assay. The results are shown in table (3) and discussed on page 2988, left column, fourth paragraph.

It is found that MBP107 (and a mutated version, MBPala) lacked biological activity in the cell fusion assay. Although the reason for this is unclear, the results were commented by the authors of document (16) as not being unexpected, "... since the MBP carrier represents

approximately 90% of the total protein mass" and may sterically hinder the accessibility of DP107 for its target site.

20. The information given in this part of document (16) does not allow to discern if the monomeric form or the tetrameric form of MBP107 has been tested in the cell fusion assay, as in both cases the carrier represents approximately 90% of the total protein mass.

The antifusogenic peptide-maleimide-albumin conjugates used according to the patent in suit have a molecular mass of approximately 70 kDa (94% thereof are represented by the carrier).

Document (16) does not contain a clear statement that conjugates having a lower molecular mass than the presently claimed conjugates (monomeric MBP107 has a molecular mass of 50 kDa) do not perform antifusogenic activity due to steric hindrance. However, the Board is convinced that the disclosure in this prior art document would rather detain a skilled person trying to solve the technical problem underlying the patent in suit to modify an antifusogenic peptide by conjugating it to a large molecule, such as albumin. This all the more so as at the relevant date numerous methods to increase the in-vivo half-life of therapeutically active peptides were known, which all were more promising (see point (16) above). The Board notes in this respect that the existence of these promising methods was not disputed by the Respondent in the written procedure.

21. The Respondent argued that a skilled person at the relevant date of the patent in suit knew that antifusogenic peptides could be coupled to molecules of twice the size of serum albumin without losing their antifusogenic activity as a result of steric hindrance.
22. He refers to document (17) which investigates the antifusogenic activity of synthetic peptides DP107 and DP178 of HIV-1. The document contains the results of cell fusion- and HIV-1 neutralization assays. It discloses the preparation and testing of a construct designated M41 - P, which contains MBP coupled via a linker to DP178. The linker comprises a mutated peptide DP107 (Ile to Pro at position 578). This disrupts the interaction between DP107 and DP178 (see Fig.1 on page 3772) and enables the interaction of the DP178 sequence with its target.

The conjugate of document (17) is distinguished from the conjugates according to the patent in suit by the presence of a very long linker between the carrier molecule and the antifusogenic peptide. As can be seen from the chapter "Construction of fusion proteins and mutants" on page 3771, right paragraph, this linker consists of 103 amino acids resulting from gp41 (the mutated DP107) plus additional 14 amino acid residues from a 10-glutamine residue spacer and the four-residue factor X<sub>a</sub> digestion site, contained in the pMal - p2 vector which is described in more detail in document (16) (see point (17) above).

The conjugates used according to the present claims contain either no linker at all or one of the short linkers AEA or AEEA and have therefore definitely a

different structure. At best, document (17), although not mentioning the technical problem underlying the patent in suit, namely to extend the in vivo half-life of antifusogenic peptides, could be considered to add one more method to modify the antifusogenic peptides of document (1) to the list of alternative methods already known to the skilled person (see point (15) above). It does not, however, contain any information that would prompt the skilled reader to combine the disclosure of documents (1) and (4).

23. Following another line of argumentation, the Respondent refers to document (12), which in Annex II refers to human monoclonal antibody 2F5, which targets the fusogenic subunit of gp41 using residues 662 to 667. This target sequence forms part of peptide DP178. The size of an average IgG molecule is about 150 kDa, thus twice the size of the conjugates of the present invention. The Respondent concludes that it followed from document (12), Annex II, that, at the priority date, large gp41 directed protein inhibitors were expected to be successful antifusogenic agents and that no problem of steric hindrance, resulting from the size of such molecules, had to be apprehended.

This conclusion is not substantiated by verifiable facts. No evidence has been provided that 2F5, or any other anti gp41 monoclonal antibody, has antifusogenic activity. In fact, the chapter of document (12), Annex II, from which the Respondent cites, has the title "Inability to Elicit Neutralization of HIV Infection using Monoclonal Antibody". Accordingly, Respondent's argument must fail.

24. Finally the Respondent refers to document (11) disclosing a peptide, designated CS3, consisting of 17 amino acids from gp41, which "retains activity when fused to serum albumin" (see Respondent's letter, dated 26 October 2005, page 5, point 3.12).

CS3, which is also designated DP116, is referred to in document (1), page 363, lines 28 to 33, originating from the Respondent, where it is said that the peptide previously has been shown to be ineffective as a HIV inhibitor. Document (1) refers in this respect to document (8), which on page 10539, left column lines 40 to 42 reports that CS3 (DP116) exhibited no evidence of antifusogenic activity.

25. To summarise, the skilled person trying to solve the problem underlying the patent in suit, namely to provide medicaments for the prevention and/or treatment of viral infections having increased in vivo stability whilst at the same time retaining their antifusogenic activity, was aware of a number of alternative procedures to increase the in vivo therapeutic half-life of the antifusogenic peptides known from document (1) (see point (16) above). The situation he/she was facing cannot be compared with what is called a "one-way-street" situation.
26. Although it cannot be derived with certainty from document (16) that conjugating of an antifusogenic peptide to a moiety of about the size of albumin will inevitably lead to steric hindrance problems as a result of the very limited three dimensional space at the environment in which an antifusogenic peptide is required to show activity, the document at least points

to problems which may result from the high mass of the carrier (90% of the conjugate). A skilled person, being aware of more promising methods, would, in the Board's view, take this into consideration (see point (20) above).

None of the prior art documents on file contains information that would have convinced the skilled person that the expectation of steric hindrance, as hinted at in document (16) was unfounded.

27. The Board, therefore, arrives at the decision that a skilled person at the relevant date of the present invention, would not have considered to conjugate antifusogenic peptides via a maleimide group, either with or without a short linker, to serum albumin, a protein with a molecular mass of 66 kDa, in order to provide medicaments for the prevention and/or treatment of viral infections having increased in vivo stability whilst at the same time retaining their antifusogenic activity.

The subject-matter of claims 1 to 25 of Appellant's new main request cannot be derived in an obvious way from the disclosure in document (1) upon combination with the disclosure in document (4) and therefore involves an inventive step according to the requirements of Article 56 EPC.

*Sufficiency of disclosure - Article 83 EPC*

28. Claims 1 to 25 refer to the use of modified peptides, or of compositions comprising them, for the preparation of medicaments for preventing and/or treating viral infections.

Where a therapeutic application is claimed in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, under Article 83 EPC the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application (cf decision T 609/02 of 27 October 2004, point (9) of the reasons for the decision).

Taking into account the intrinsic difficulties for a compound to be officially certified as a drug, it is the practice of the Boards of Appeal that for acceptance of a sufficient disclosure of a therapeutic application in a patent/patent application, it is not always necessary that results of clinical trials are provided at the relevant date, but that it is required that the patent/patent application provides some information to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease.

Once this evidence is available from the patent/patent application, then post-published evidence may be taken into account to support the disclosure in the patent application.

29. The Board, in the present case, is convinced that the application as published provides sufficient information that the modified anti-viral and antifusogenic peptides have a direct effect on the metabolic mechanism of viral infections. The used



peptides are known from the disclosure in document (1) to have anti-viral and antifusogenic activity. The medical use of the peptides and different ways of their administration to patients in need thereof is as well described in the application as published as a method for detecting the extended presence of the modified peptides in a patient's blood by a specific immunoassay.

The experimental data provided in post-published document (18) support the disclosure in the application as published.

Accordingly, the Board is satisfied that the patent application discloses the invention according to claims 1 to 25 of the new main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 25 of the new main request submitted during the oral proceedings and a description still to be adapted thereto.

Registrar:

S. Sanchez Chiquero



Chair:

U. Kinkeldey